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PRELIMINARY AMENDMENT	Attorney Docket Confirmation No.	DURE-002DIV N/A
	First Named Inventor	Edward M. Gillis et al.
Address to: Box Patent Application Assistant Commissioner for Patents Washington, D.C. 20231	Application Number	Unassigned
	Filing Date	Herewith (January 28, 2002)
	Group Art Unit	3763
	Examiner Name	Unassigned
	Title	"Composite Drug Delivery Catheter"

Sir:

Prior to examination of the application on the merits, please enter the following amendments:

AMENDMENTS

IN THE SPECIFICATION

At page 1, following the title, insert the following:

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CROSS-REFERENCE TO RELATED APPLICATION

This application is a divisional of prior U.S. application serial no. 09/399,465, filed June 23, 1999, now pending. --

IN THE CLAIMS

Please cancel claims 1-33 without prejudice.

Please replace 34-40 with claims 34-40 below. Amended claims are indicated by parenthetical text at the beginning of the claim.

Add new claims 41- 52.

34. **(Amended)** A method for delivery of a drug to a treatment site in a subject, the method comprising the step of:

implanting a composite catheter into a subject, the composite catheter comprising:

an outer member comprising a proximal end, a distal end, and an outer member body defining an outer member lumen; and

an inner member comprising a proximal end, a distal end, and an inner member body defining an inner member lumen, wherein the inner member is interposed within the outer member lumen so as to define an interstitial space between the inner member and the outer member, wherein the inner member body comprises a substantially

impermeable material selected from the group consisting of a polymer, metal, glass, a polyolefin, nylon, polyethylene terephtholate, urethane, a fluorenated polymer, poly(methyl)methacrylate, polyvinylidine chloride, laminous hydrophilic polymer, laminous hydrophobic polymer, acrylonitrile, nickel titanium, superelastic nickel titanium, and laminates of hydrophilic and hydrophobic polymers, and wherein the inner member lumen defines a drug delivery conduit suitable for delivery of a drug from the inner member proximal end to the inner member distal end,

wherein said implanting provides a drug delivery pathway from a proximal end of the catheter, through the inner member lumen to a distal end of the catheter, and out a drug delivery outlet positioned at a treatment site in a subject; and

introducing a drug into the inner lumen of the catheter;

wherein the drug is delivered to the treatment site in the subject.

35. The method of claim 34, wherein the inner member lumen is suitable for delivery of the drug at a low volume delivery rate.

36. The method of claim 35, wherein the low volume delivery rate is from about 0.01 μl/day to about 200 μl/day.

37. The method of claim 34, wherein the catheter is substantially filled with the drug prior to implanting.

38. The method of claim 34, wherein the catheter further comprises a distal extension at the distal end of the catheter, wherein the distal extension is flexible.

39. The method of claim 34, wherein the treatment site is subcutaneous, percutaneous, intravenous, intrathecal, intramuscular, intra-arterial, intravascular, intraperitoneal, intraspinal, epidural, intracranial, intracardial, peritumoral, or intratumoral.

40. **(Amended)** The method of claim 35, wherein the treatment site is a site within a kidney, liver, pancreas, heart, lung, eye, ear, lymph node, breast, prostate, ovary, testicle, thyroid, spleen, central nervous system, skeletal muscle, bone, lymph vessel, artery, arteriole, capillary bed, blood vessel, vein, peripheral nervous system, digestive system, gastrointestinal tract, urinary bladder, gall bladder, adrenal gland, adipose tissue, parathyroid gland, uterus, fallopian tube, skin, tumorous growth, autologous graft, synthetic graft, or site of microbial infection.

Add the following new claims:

-- 41. **(New)** A method for delivery of a drug to a treatment site in a subject, the method comprising the step of:

implanting a composite catheter into a subject, the composite catheter comprising:

an outer member comprising a proximal end, a distal end, and an outer member body defining an outer member lumen, wherein the outer member body comprises a substantially biocompatible material selected from the group consisting of silicone, polyethylene, an ethylene vinyl acetate copolymer, a polyvinylchloride, polymethylmethacrylate, polyethylmethacrylate, polymethacrylate, ethylene glycol dimethacrylate, ethylene dimethacrylate, hydroxymethyl methacrylate, polyurethane, polyvinylpyrrolidone, 2-pyrrolidone, polyacrylonitrile butadiene, a polycarbonate, polyamides, a fluoropolymers, a polystyrene, a styrene acrylonitrile homopolymer, a styrene acrylonitrile copolymer, cellulose acetate, an acrylonitrile butadiene styrene homopolymer, acrylonitrile butadiene styrene copolymer, polyvinylchloride, silicone rubber, polymethylpentene, a polysulfone, a polyester, a polyimide, polyisobutylene, polymethylstyrene, a polyvinyl chloride elastomer, a polyolefin homopolymeric elastomer, a polyolefine copolymeric elastomer, a urethane-based elastomer, a natural rubber, and a synthetic rubber; and

an inner member comprising a proximal end, a distal end, and an inner member body defining an inner member lumen, wherein the inner member is interposed within the outer member lumen so as to define an interstitial space between the inner member and the outer member, and wherein the inner member lumen defines a drug delivery conduit suitable for delivery of a drug from the inner member proximal end to the inner member distal end,

wherein said implanting provides a drug delivery pathway from a proximal end of the catheter, through the inner member lumen to a distal end of the catheter, and out a drug delivery outlet positioned at a treatment site in a subject; and

introducing a drug into the inner lumen of the catheter;

wherein the drug is delivered to the treatment site in the subject.

42. **(New)** The method of claim 41, wherein the inner member lumen is suitable for delivery of the drug at a low volume delivery rate.

43. **(New)** The method of claim 42, wherein the low volume delivery rate is from about 0.01 µl/day to about 200 µl/day.

44. **(New)** The method of claim 41, wherein the catheter is substantially filled with the drug prior to implanting.

45. **(New)** The method of claim 41, wherein the catheter further comprises a distal extension at the distal end of the catheter, wherein the distal extension is flexible.

46. **(New)** The method of claim 41, wherein the treatment site is subcutaneous, percutaneous, intravenous, intrathecal, intramuscular, intra-arterial, intravascular, intraperitoneal, intraspinal, epidural, intracranial, intracardial, peritumoral, or intratumoral.

47. **(New)** A method for delivery of a drug to a treatment site in a subject, the method comprising the step of:

implanting a composite catheter into a subject, the composite catheter comprising:

an outer member comprising a proximal end, a distal end, and an outer member body defining an outer member lumen;

an inner member comprising a proximal end, a distal end, and an inner member body defining an inner member lumen, wherein the inner member is interposed within the outer member lumen so as to define an interstitial space between the inner member and the outer member, and wherein the inner member lumen defines a drug delivery conduit suitable for delivery of a drug from the inner member proximal end to the inner member distal end; and

a support member positioned within the interstitial space, wherein the support member comprises a material selected from the group consisting of metal, a metal alloy, carbon fiber, a polycarbonate, a polymer, plexiglass, stainless steel, parylene-coated stainless steel, Teflon-coated stainless steel, and nickel titanium,

wherein said implanting provides a drug delivery pathway from a proximal end of the catheter, through the inner member lumen to a distal end of the catheter, and out a drug delivery outlet positioned at a treatment site in a subject; and

introducing a drug into the inner lumen of the catheter;

wherein the drug is delivered to the treatment site in the subject.

48. **(New)** The method of claim 47, wherein the inner member lumen is suitable for delivery of the drug at a low volume delivery rate.

49. **(New)** The method of claim 48, wherein the low volume delivery rate is from about 0.01 µl/day to about 200 µl/day.

50. **(New)** The method of claim 47, wherein the catheter is substantially filled with the drug prior to implanting.

51. **(New)** The method of claim 47, wherein the catheter further comprises a distal extension at the distal end of the catheter, wherein the distal extension is flexible.

52. **(New)** The method of claim 47, wherein the treatment site is subcutaneous, percutaneous, intravenous, intrathecal, intramuscular, intra-arterial, intravascular, intraperitoneal, intraspinal, epidural, intracranial, intracardial, peritumoral, or intratumoral. --

REMARKS

Formal Matters

Claims 34-52 are pending after entry of the amendments set forth herein.

Claims 1-33 are canceled without prejudice as being drawn to a non-elected invention.

Claims 34 and 40 are amended.

New claims 41-52 are added.

Claim 34 is amended to incorporate the elements of claim 5 as originally presented. No element of claim 5 is amended, and thus each element of claim 34 is entitled to the full scope of equivalents under the doctrine of equivalents.

Claim 40 is amended to correct a typographical error.

Support for new claims 41-52 is found in original claims 34-40, and in original claims 1, 5, 7, and 9.

Attached hereto is a marked-up version of the changes made to the specification by the current amendment. The attached is captioned **"VERSION WITH MARKINGS TO SHOW CHANGES MADE."**

No new matter has been added.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number DURE-002DIV.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: January 28, 2002

By: _____
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Registration No. 36,513

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Cancel claims 1-33.

34. **(Amended)** A method for delivery of a drug to a treatment site in a subject, the method comprising the step of:

implanting [the composite catheter of claim 1] **a composite catheter** into a subject, **the composite catheter comprising:**

an outer member comprising a proximal end, a distal end, and an outer member body defining an outer member lumen; and

an inner member comprising a proximal end, a distal end, and an inner member body defining an inner member lumen, wherein the inner member is interposed within the outer member lumen so as to define an interstitial space between the inner member and the outer member, wherein the inner member body comprises a substantially impermeable material selected from the group consisting of a polymer, metal, glass, a polyolefin, nylon, polyethylene terephtholate, urethane, a fluorenated polymer, poly(methyl)methacrylate, polyvinylidine chloride, laminous hydrophilic polymer, laminous hydrophobic polymer, acrylonitrile, nickel titanium, superelastic nickel titanium, and laminates of hydrophilic and hydrophobic polymers, and wherein the inner member lumen defines a drug delivery conduit suitable for delivery of a drug from the inner member proximal end to the inner member distal end,

wherein said implanting provides a drug delivery pathway from a proximal end of the catheter, through the inner member lumen to a distal end of the catheter, and out a drug delivery outlet positioned at a treatment site in a subject; and

introducing a drug into the inner lumen of the catheter;

wherein the drug is delivered to the treatment site in the subject.

40. **(Amended)** The method of claim 35, wherein the treatment site is a site within a kidney, liver, pancreas, heart, lung, eye, ear, lymph node, breast, prostate, ovary, testicle, thyroid, spleen, central nervous system, skeletal muscle, bone, lymph vessel, artery, arteriole, capillary bed, blood vessel, vein, peripheral nervous system, digestive system, gastrointestinal tract, urinary bladder, gall bladder, adrenal gland, adipose tissue, parathyroid gland, uterus, fallopian tube, skin, tumorous growth, autologous graft, synthetic graft, or site of microbial **[**infeciton**]** <u>**infection**</u>.

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	First Named Inventor	Edward M. Gillis et al
	Group Art Unit	1763
	Attorney Docket No.	DURE-002DIV

Sir:

Enclosed are Seven (7) sheets of formal drawings submitted with the Initial Filing of the above-referenced application.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: January 28, 2002

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